I. Scope of Work

Independently and not as an agent of the Government, the contractor shall furnish the necessary personnel, materials, services, facilities, except as provided in the schedule, and otherwise do all things necessary for or incident to the performance of the work as described below:

A. Background

The Medicated Feeds Program has been implemented with the assistance of the states under contract since 1973. For the last several years states have accomplished surveillance inspections to determine whether firms manufacturing medicated feeds were in compliance with key good manufacturing practices (GMP) regulations.

The Second Generation Medicated Feeds Regulations, published by the FDA in 1986, set forth revised requirements concerning approval procedures for the manufacture of animal feeds containing new animal drugs. These regulations focus on high-risk drugs, i.e., carcinogens and drugs requiring withdrawal times at their lowest use level. Firms using Category II Type medicated articles to make medicated feeds are required to register with FDA and hold approved licenses. FDA is required to inspect these firms once every two years.

FDA's Center for Veterinary Medicine (CVM) uses the Current Good Manufacturing Practices (CGMP) inspection classification to determine the approval decisions for pending license applications. Classification of OAI will result in recommendations to refuse license approvals, while NAI and VAI classifications will not. An OAI classification for a licensed firm may start the process to withdraw the license.

On June 5, 1997, FDA published a final rule prohibiting the use of mammalian protein in ruminant feeds. This action was taken to prevent the spread of bovine spongiform encephalophy (BSE) in the United States; thus, the phrase "BSE rule" to describe it. The rule, which is codified in 21 CFR 589.2000, provides for labeling, record keeping and clean out requirements for renderers, feed manufacturers, haulers of feed, and producers.

B. Objectives:

This contract is designed to obtain state assistance in the inspectional coverage of medicated feed establishments, specifically:

1. To conduct inspections of medicated feed establishments to determine compliance with the Federal Food, Drug, and Cosmetic Act

(FD&C Act) and State feed law (if the contractor's feed law has the provisions of the current AAFCO Uniform State Feed Bill).

2. To encourage voluntary corrective action by the establishment when appropriate.

3. To furnish the FDA with reports of inspections and sample examinations accomplished under the contract. Reports on any compliance follow-up and corrections achieved by the contractor under its own program will also be submitted.

4. Assuring compliance with 21 CFR 589.2000 by the medicated feed establishments, both licensed and non-licensed.

C. Inspection Coverage

In performance hereof the contractor shall conduct medicated feed inspections of licensed medicated feed establishments and "BSE Rule" compliance inspections only of licensed and/or non-licensed medicated feed establishments if requested by the Agency.

The establishments to be inspected by the contractor will be those required to register with FDA by Section 510 of the FD&C Act because they manufacture medicated feeds from Category II, Type A Articles (21 CFR 207) which do now or will require an approved license. These establishments are included in FDA's active Official Establishment Inventory. Non-registered establishments may be inspected as a follow-up to a tissue residue investigation that implicates a feed mill as the source of the contaminant or for compliance with the requirements of 21 CFR 589.2000. These manufacturing sites are required to comply with a different set of CGMP regulations (i.e., 21 CFR 225.120 et. seq.). Both registered and non-registered establishments have the same requirements with regard to the BSE rule.

To preclude duplication with those inspections, which will be accomplished by FDA personnel, the specific inspections to be performed by the Contractor will be planned and/or scheduled by the FDA regional/district office in conjunction with the Contractor. Joint inspections with FDA personnel to achieve nationwide uniformity, training, evaluation, etc., may be included.

Assignment of establishments by FDA for coverage under the contract will take into consideration the following :

1.Inspection Priorities

The following inspection priorities apply to firms using Category II Type A medicated articles in the manufacture of Type B and/or C medicated feeds.

a. Re-inspections (Priority 1)

Conduct re-inspections of firms whose most recent inspection were classified OAI due to either CGMP or non-CGMP deviations, except for firms in the pre-approval mode. Re-inspection of the OAI firm should occur within 90 days of issuance of a Warning letter to determine whether CGMP violations are continuing.

When CVM receives license application from a firm in violative status (i.e., classification of OAI because of CGMP deviations), CVM is advising the firm that its applications cannot be approved.

b. Pre-Approval Inspections (Priority 2)

Conduct pre-approval inspections of all firms submitting license applications for the first time. This inspection is required to take place before a license application can be approved and should take place within 60 days of the filing of license application. FDA has a 90-day statutory obligation to act on a license application. If the inspection is not made, CVM is obligated by the Act to approve the license application.

New applicants may be newly constructed or acquired facilities, or active feed mixers that wish to secure a license. A new facility does not have to be in operation to demonstrate capability and obtain license approval. The investigator must determine the applicant’s knowledge of the CGMP requirements and preparedness to comply.

c. BSE Inspections (Priority 3)

Conduct inspections of both licensed and non-licensed medicated feed establishments for compliance with the requirements of 21 CFR 589.2000. Similar inspections are to be done when inspecting establishments under priority 1, 2 or 4.

d. Biennial Inspections (Priority 4)

Conduct biennial CGMP inspections of registered firms whose most recent CGMP inspection was classified NAI and VAI.

2. Method of Coverage

a. General Procedures

The activities under the contract will be conducted using the procedures, techniques, and reporting forms specified by FDA in the current Medicated Feeds Program (CP7371.004), the applicable sections of which are incorporated by reference, and in the special assignment for BSE inspections. The Government will furnish copies to the contractor. The FDA regional/district office will provide guidance and interpretations as necessary.

The contractor shall conduct inspections of these establishments using state officials who have been commissioned as officers of the Department of Health and Human Services, Food and Drug Administration, under the authority of the Federal FD&C Act. Under commission, conformance with the procedural requirements of the Federal FD&C Act is required including use of credentials, and issuance of Notice of Inspection, Inspectional Observations, and Receipt for Sample forms.

b. Type of Inspection

The contractor shall conduct surveillance inspections to determine compliance with the CGMP requirements where CVM or a firm has requested a pre-approval inspection (Priority 2 above), or the firms require biennial inspection (Priority 4 above).

The contractor shall conduct "BSE Rule" compliance inspections at both the licensed and non-licensed medicated feed firms. Follow the directions attached, "Inspections for Compliance with 21 CFR 589.2000" and complete the form, "Report of Inspection for Compliance with 21 CFR 589.2000". Also, the FDA Guidance for Industry 68, "Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers and Distributors" should be given to the medicated feed establishment that is being inspected.

The Medicated Feed Inspection Report (Form FDA-2481) shall be completed by the contractor for each CGMP inspection. All deviations from the items on the report, i.e. each NO answer, must be fully explained (and documented, if possible) in the narrative section of the form. The report shall contain sufficient information on deviations to facilitate a FDA decision on whether or not to approve a license, and whether a comprehensive inspection is warranted.

In addition to the CGMP elements on the Form FDA-2481, the contractor shall look for other possible non-CGMP violations. Be alert for possible sales of prescription animal drugs and determine whether these drugs are sold on the order of a licensed veterinarian. Also look for other possible non-CGMP violations, such as the manufacture of medicated feeds without required approvals, illegal combinations, and unapproved sources of drugs, such as soluble powders and bulk drug substances. Report any activity on the form FDA 2481.

Pre-approval inspections are surveillance CGMP inspections of medicated feed firms submitting a license application for the first time or for firms that have been placed in the Auxiliary OEI. The contractor may be assigned firms for pre-approval inspections by the district based on a request from the Center for Veterinary Medicine (CVM). As the Center has a statutory 90-day timeframe to act on the application of the license, these inspections should be completed as soon after assignment as possible.

Routine inspections shall not be made more frequently than once every two years to satisfy the statutory biennial requirement. Reinspections as a follow-up to non-OAI violative practices may be made under this contract when assigned by the FDA district.

Inspection visits are incomplete inspections where the Form FDA-2481 is not used because the establishment is found to be out of business, inactive, or not an OEI obligation. Information on inspection visits shall be submitted on a computer generated coversheet form.

Joint inspections with FDA personnel to achieve nationwide uniformity, training, or evaluation will be planned from time to time and may be included within the inspections to be accomplished under this contract.

The Compliance Program covers two other types of inspections, i.e., comprehensive and non-CGMP, which will not be accomplished by the states under this contract unless assigned by the FDA district to appropriately trained states. The comprehensive is an in-depth evidence gathering inspection made to document violations for federal regulatory action consideration. The non-CGMP inspection involves documentation of violations regarding the sale or use of premixes (Type A medicated articles) by distributors or feed mills without required approvals.

Compliance actions are not provided for under this contract. However, the Contractor may wish to pursue any necessary compliance follow-up to violative conditions under the state's program. Any state actions shall be coordinated with the FDA district. The warning letter for an OAI classification must be signed by the FDA District Director and must contain the specific language stated in the Compliance Program.

c. Samples

Physical samples will not normally be collected during surveillance CGMP or BSE inspections. An exception occurs under the circumstances detailed in the Medicated Feed Compliance Program where cross contamination with specific drugs could occur. If there is a likelihood that the state laboratory analysis could confirm cross contamination using appropriate methodology, a sample may be included under this contract. Information on the sample collection and analysis shall be reported on state forms.

d. Quality Control

FDA will evaluate contractor performance throughout the contract period. This will be accomplished by a variety of techniques, including: review of reports, joint inspections (included as contract inspections), and independent reinspection by FDA. Independent quality control reinspections (audits) may be made by FDA to facilitate an evaluation of the overall performance of the Contractor, and will be scheduled by the FDA regional/district office. Findings of the independent FDA quality control reinspections will be provided to the Contractor for review and information.

II. Reports/Deliverables

The Contractor shall submit the following reports/deliverables by the due dates indicated:

A. Inspection Reports - SUBMIT NO LATER THAN 15 WORKING DAYS AFTER THE DATE OF THE STATE INSPECTION TO THE FDA DISTRICT OFFICE

The contractor shall complete the Medicated Feeds Inspection Report, Form FDA-2481, and the Computer Generated Coversheet, (Form FDA-481-CG), Parts A, C, and E, and, where appropriate, the contractor shall use the FDA Product Code List to complete the appropriate sections of the Coversheet, including Part C, Products Covered where the products inspected will be recorded. Also, corrective actions shall be reported and coded

on part E of the coversheet under the newly revised Compliance Achievement Reporting System, which replaces the Voluntary Correction Reporting System. The government will furnish the necessary FDA forms.

SUBMIT NO LATER THAN 15 WORKING DAYS AFTER THE DATE OF THE STATE INSPECTION TO THE FDA DISTRICT OFFICE.

NOTE:

PAC codes for Coversheet:
71S007 – BSE-Medicated State Contract Inspections (Licensed)
71S008 – BSE-Medicated State Contract Inspections (Non-Licensed)

The Contractor shall complete the BSE checklist titled "Report of Inspection for Compliance with 21 CFR 589.2000" and the Computer Generated Coversheet, (Form FDA-481-CG), Parts A, C, and E, and, where appropriate, the contractor shall use the FDA Product Code List to complete the appropriate sections of the Coversheet, including Part C, Products Covered where the products inspected will be recorded and shall be completed and submitted to the FDA District Office no later than 15 working days after the inspection. Also, the FDA Guidance for Industry 68, "Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers and Distributors" should be given to the medicated feed establishment that is being inspected.

B. Sample Reports - SUBMIT UPON COMPLETION TO FDA DISTRICT OFFICE

All samples analyzed shall be reported to FDA on forms used by the state. Additionally, worksheets or other more detailed information on the analyses will be submitted to FDA for those samples found not to be in compliance, or where a question exists whether or not a sample is violative,

C. Compliance Action Reports - SUBMIT UPON COMPLETION TO FDA DISTRICT OFFICE

Copies of the documents used by the state to record compliance actions shall be furnished to the appropriate FDA district office upon completion.

D. Quarterly Summary Report - SUBMIT NO LATER THAN 30 DAYS AFTER END OF EACH 90 DAY REPORTING PERIOD TO:

1. One copy to: FDA District Office
2. Two Copies to:
   Food and Drug Administration
   Div. of State Contracts and Assistance
   Management, HFA-521,
   Room 3-40, Park Building
   5600 Fishers Lane
   Rockville, Maryland 20857

For each 90-day period of the contract (based upon the performance period), a Quarterly Summary Report (Form FDA-2684a) on the inspections, samples, and actions shall be prepared. Included with the report shall be the contract number, a list of the establishments inspected specifying the name and city of the firm inspected, inspection date, type of inspection (priority 1, 2, 3 or 4) and number of samples collected. Where visits were encountered, they should also be noted. NOTE: In those periods where no inspections were performed a quarterly report showing no inspections is required.

E. Receipt and Acceptance Supplies/Services

The supplies and-or services delivered hereunder shall be inspected and accepted at the destination by the Contracting Officer's Representative (COR) specified below. If the supplies or services are acceptable, the COR shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the COR shall document the nonconforming items/services and immediately notify the Contracting Officer. The COR for this order is : Glenn Johnson, 301-827-2907.

III. Administrative Data

A. GOVERNMENT FURNISHED MATERIALS

The following forms required for use in the performance of the services required hereunder will be furnished by the Government. Delivery will be made in a timely manner to the contractor's facility, such that the required services can be performed within the effective dates of the contract.

Form No.	Title
FDA-2481	Medicated Feed Inspections Reports
FDA-481-CG	Computer Generated Coversheet (Parts A, C, and E)

FDA-2684a State Contract Quarterly Medicated Feed Report
FDA-482 Notice of Inspection

FDA-483 Inspectional Observations

FDA-484 Receipt of Samples

Inspection for Compliance with 21 CFR 589.2000 for Feed Manufacturers, Protein Blenders, Distributor

Report of Inspection for Compliance with 21 CFR 589.2000

FDA Guidance for Industry 68, "Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers and Distributors"

B. INVOICE SUBMISSION (F-P) - Quarterly

1. An original and two (2) copies shall be submitted to the address cited in Block #21 of the FDA-3303 – "Order for Supplies or Services".

2. In addition, one informational copy of all vouchers shall be submitted to the Co-Project Officer in the Regional/ District Office designated by separate correspondence.

3. Questions relating to when payment will be received should be directed to the FDA Payment Office at telephone number 301-827-5007.

IV. SIMPLIFIED ACQUISITION TERMS AND CONDITIONS

A. Clauses Incorporated by Reference (FAR 52.252-2 FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at the following address:

www.arnet.gov/far

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1)

CLAUSES

52.213-4 Terms and Conditions-Simplified Acquisitions (Other Than Commercial Items) (FEB 2000)

V. List of Other Attachments :

Attachment 2: Small Entities Compliance Guide
Attachment 3: Inspections for Compliance w/ 21 CFR 589.2000
Attachment 4: Report of Inspection for compliance w/ 21 CFR 589.2000

FDA GUIDANCE FOR INDUSTRY 68

This guide replaces those parts of Guidance for Industry 60, June 17, 1997, that applied to protein blenders, feed manufacturers, and distributors.

SMALL ENTITIES COMPLIANCE GUIDE

FOR PROTEIN BLENDERS, FEED MANUFACTURERS, AND DISTRIBUTORS

This document is intended to provide guidance for "ANIMAL PROTEINS PROHIBITED FROM USE IN RUMINANT FEED," Title 21, Code of Federal Regulations, Part 589.2000, Effective Date: August 4, 1997.

Submit comments and requests for information to Gloria Dunnavan, Director, Division of Compliance (HFV-230), U.S. Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Room 405, Rockville, MD 20855, (301) 594-1726.

The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This guidance document represents the agency's current thinking on compliance with the regulation 21 CFR 589.2000 "Animal Proteins Prohibited from Ruminant Feed." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
February 1998

WHAT IS THE PURPOSE AND SCOPE OF THIS REGULATION?

This regulation is designed to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE), sometimes referred to as "Mad Cow Disease," through animal feed. The regulation prohibits the use of certain proteins derived from mammalian tissue in feeding ruminant animals. An example is meat and bone meal made from cattle. However, certain products are **exempt** from the regulation:

- The following protein products derived from mammals are **exempt:**
  - Blood and blood products
  - Gelatin
  - Milk products (milk and milk proteins)
  - Pure porcine (pork) or pure equine (horse) protein
  - Inspected meat products, such as plate waste, which have been cooked and offered for human food and further heat processed for animal feed

- The following nonmammalian protein products are **exempt:**
  - poultry
  - marine (fish)
  - vegetable

- The following are also **exempt** because they are not protein or tissue:
  - Grease
  - Fat
  - Amino acids
  - Tallow
  - Oil
  - Dicalcium phosphate

If you receive and process **ONLY** the above exempted products (or only products containing the exempted products) you are not required to comply with this regulation. We refer to this material as **"nonprohibited material**."

All other mammalian protein will be referred to as "**prohibited material**" throughout this guide. If you receive and process this material or products containing this material, you must comply with this regulation.

Ruminant animals are any animals with a four-chambered stomach including cattle, sheep, goats, buffalo, elk, and deer.

IS MY FIRM AFFECTED BY THIS REGULATION?

This regulation defines blenders, feed manufacturers, and distributors as follows -

- "Blender" means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal product. "Blenders" under the regulation are protein blenders, which are intermediaries between renderers and feed manufacturers.

- "Feed manufacturer" includes manufacturers and mixers of complete and intermediate feeds intended for animals. It includes on-farm feed mixing operations; however, those with on-farm mixers should refer to the separate guide for feeders of ruminant animals with on-farm feed mixing operations (FDA Guidance for Industry 69). The term includes pet food manufacturers.

- "Distributor" includes persons who distribute or transport feeds or feed ingredients intended for animals. **This includes retailers of feed and feed products; the distribution activities of blenders and feed manufacturers; and independent haulers.**

***** Even if you fall within the definition of blender, feed manufacturer, or distributor, you are not subject to the regulation if you do not receive, process and distribute any prohibited material or products containing prohibited material.

If you know or have reason to know that an incoming product contains or may contain prohibited material, you are subject to the regulation. Renderers may not be able to determine the species of incoming material; rendered product from such material is considered “prohibited material” because it **"contains or may contain"** prohibited material. You may wish to have assurance from your raw material supplier about the product’s contents. This could include a certification from the supplier, or specification of source in a business contract.

The regulation provides procedures for two general categories of blenders, feed manufacturers, and distributors that are subject to the regulation: those that do **NOT** separate prohibited material from nonprohibited material, and those that do.

HOW DO I COMPLY WITH THE NEW REGULATION?

A. Firms That Handle Only Prohibited Material, or Handle Both Prohibited and Nonprohibited Material But Do Not Separate Them Need to:

1. Label all outgoing products that contain or may contain prohibited material with the following cautionary statement:

"Do not feed to cattle or other ruminants."

2. Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the records available for inspection and copying. Invoices or similar documents for incoming and outgoing products will satisfy this requirement. The records should contain information normally expected to be included in such documents -

- Date of the receipt or purchase and sale or delivery
- Name and address of the seller
- Name and address of the consignee
- Identification of the product
- Quantity

3. Maintain the records for a minimum of one year.

B. Firms That Do Separate Prohibited from Nonprohibited Materials Have Two Additional Requirements:

4. Provide for measures to avoid commingling or cross-contamination of prohibited and nonprohibited materials.

5. Maintain written procedures that document the measures you adopt to prevent commingling or cross-contamination.

WHAT DO I NEED TO KNOW ABOUT THE CAUTIONARY STATEMENT?

■ The term "label" means a display of written, printed, or graphic matter on the immediate container of any product. The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

■ The cautionary statement is required only if the products contain or may contain prohibited material.

■ This requirement does **NOT** apply to **pet food products** that are sold or intended for sale at retail or to feeds for **nonruminant laboratory animals**. If the pet food products or laboratory animal feeds are sold or are intended for sale as distressed or salvage items, then the cautionary statement is required. Distressed or salvage items may be fed to or become components of feed for other animals including ruminants.

■ Labeling for all other animal feeds is required to contain the cautionary statement, **including feeds intended for nonruminant animals**.

■ The statement must be placed prominently on the label or labeling. It should be conspicuous compared with other statements on the labeling. It should be placed on the labeling so that it is likely to be read and understood by the ordinary individual under usual conditions of purchase and use.

■ FDA suggests that the cautionary statement have a different type size or color from other labeling, or that you use some other means of highlighting the statement so that it is easily noticed by the purchaser.

■ For products shipped in bulk, the cautionary statement should appear on the invoice or other document, and placard or any other labeling that physically accompanies the shipment.

■ For products that are shipped in bags or other small containers, the cautionary statement should appear on the product labels. The labels can be attached to or be part of the bag or other container.

■ The statement should be included on any other labeling for the products. This can include leaflets, brochures, and other labeling materials whether or not they physically accompany the shipment of the products. An example might be a sales brochure that you mail to current and potential customers.

WHAT DO I NEED TO KNOW ABOUT THE RECORD KEEPING REQUIREMENT?

- You are not required to create a new set of records. The information should be available in normal and customary business records maintained by you and/or your company.

- The information could be maintained in several different documents including invoices, receiving tickets, receiving logs, disbursement records, weight tickets, purchase orders, or other business records or documents.

- The records can be maintained for a shipment as a whole and do not have to be maintained for each individual container within a shipment.

- Records need to identify the product:

    - Use of the product's common or usual name on the invoice or similar sales document will satisfy, in part, the "records" requirement of the regulation as well as the legal requirement that the product label bear its common or usual name. The common or usual names of rendered products typically are those included in definitions published by the Association of American Feed Control Officials (AAFCO), such as "meat and bone meal."

    - FDA regulations permit feed labels to contain collective terms, rather than common or usual names, in certain circumstances. For example, "animal protein products" can be used where the product contains certain ingredients such as meat and bone meal. The agency will not object to continued use of collective terms, provided that feed intended for ruminants does not contain protein from prohibited material, or the product contains the cautionary statement.

- The records must be maintained so that they are available for inspection and copying. They should be maintained in a condition that keeps them legible and readily retrievable.

- Records must be maintained for one year, which means one year from the date of shipment of the product.

HOW CAN I AVOID COMMINGLING OR CROSS-CONTAMINATION?

1. <u>Separation</u>

- You could have separate equipment or facilities for the manufacture, processing, blending, or storage of prohibited and nonprohibited product. This could be entirely separate buildings, rooms, or other locations; or separate storage containers for incoming material and finished product, and separate mixers and handling equipment.

- Separate equipment for prohibited material should be clearly identified to help ensure that prohibited material is not mistakenly added to product intended to contain nonprohibited material only. **OR**

2. <u>Cleanout</u>

- Cleanout could be physical cleaning, flushing, sequencing or other means, either alone or in combination with separation measures, that are adequate to prevent carryover of prohibited material into nonprohibited material. Cleanout procedures should be used on all equipment and conveyances that handle both prohibited and nonprohibited material.

- Documentation for clean-out should include a description of how cleanout is implemented - who is responsible, how clean-out is monitored and verified; how volume of clean-out flush material was determined; and a description of how clean-out flush material is handled. **OR**

3. **<u>Combination of Separation and Cleanout</u>**

An example would be use of some separate and some common equipment (clean-out would be required for the latter).

You need **<u>written procedures</u>**, whether you use separation, cleanout, or a combination:

- Written procedures should include the procedures followed from the time of receipt of incoming material until the time of shipment of finished product. They should reflect what actually happens in your operation.

- Written procedures should have enough detail to provide a clear understanding of your actual procedures. An inspector should be able to easily identify operations that are described in the written procedures.

WHAT ARE SOME CLEAN-OUT MEASURES THAT I COULD USE?

Include one or more of the following, or other equally effective procedures. These procedures are adapted from the Current Good Manufacturing Practice for Medicated Feed regulations, Title 21, Code of Federal Regulations, Part 225.

- Use cleaning by physical means, e.g. vacuuming, sweeping, washing, etc.

- Alternatively, flushing, sequencing or other equally effective techniques may be used. Under these methods, the equipment is cleaned through use of a nonprohibited product, e.g. a feed that does not contain prohibited material.

- The volume of flushed material should be sufficient to prevent carryover of products that contain or may contain prohibited material. Due to the degree of variability among facilities, feedmills should determine their facilities' individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. The volume used should be stated in the written procedures, and should be based on a documented analysis or test of the firm's system.

- Nonprohibited material used in the cleaning should be considered prohibited and should be identified, stored, and handled so that it does not become incorporated in feed for ruminant animals.

- Sequencing should be done on a predetermined basis and be designed to prevent unsafe contamination of ruminant feeds. An appropriate example would be producing a swine feed containing prohibited material, followed by a swine or poultry feed containing nonprohibited material, followed by a ruminant feed containing nonprohibited material.

WHAT OTHER INFORMATION DO I NEED TO KNOW TO HELP ME COMPLY WITH THIS REGULATION?

- Products containing **only** nonprohibited material have no requirements under this regulation.

- The Association of American Feed Control Officials (AAFCO) has identified the following ingredients listed in their Official Publication as prohibited material:

- Meat
- Meat By-Products
- Animal Liver
- Dried Meat Solubles
- Fleshings Hydrolysate
- Meat Meal
- Meat and Bone Meal
- Animal By-Product Meal
- Meat Meal Tankage
- Meat and Bone Meal Tankage
- Hydrolyzed Hair
- Hydrolyzed Leather Meal
- Glandular Meal and Extracted Glandular Meal
- Unborn calf Carcasses
- Animal Digest
- Cooked Bone Marrow
- Leather Hydrolysate
- Meat Protein Isolate
- Mechanically Separated Bone Marrow
- Bone Meal, cooked
- Bone Meal, steamed
- Stock
- Dehydrated Garbage
- Dehydrated Food-Waste

PRODUCTS FOR IMPORT

- All mammalian protein products imported into the U.S. are subject to the same requirements under this regulation as mammalian protein obtained from domestic sources. Persons responsible for importing mammalian protein should determine the origin and species of the imported product to be assured any prohibited material is handled in compliance with this regulation. **NOTE: Importation of certain animal protein products from certain countries is prohibited by USDA regulations.**

PRODUCTS FOR EXPORT

- Product containing prohibited material that is destined for export should be marked **"FOR EXPORT ONLY"** on the shipping containers if appropriate and on documents accompanying the shipment. No other labeling would be required for purposes of this regulation but there may be additional labeling requirements imposed by the country of destination.

- Any product containing prohibited material that is destined for export and is diverted back to domestic commerce for any reason (salvage, quality, etc.), will be subject to all of the requirements of the regulation. This will include the requirement to label the product with the cautionary statement **"Do not feed to cattle or other ruminants."**

- Responsibility for these products containing prohibited material rests with the owner of the goods (holder of the title to the goods). The owner is responsible for assuring that they are not diverted back to domestic commerce unless they meet the requirements of the regulation, including the cautionary labeling statement.

ARE THERE ANY PROVISIONS FOR PROHIBITED PRODUCTS TO BE EXEMPTED FROM THIS REGULATION?

The regulation provides for two kinds of exemptions for prohibited products from the cautionary statement or records requirements:

NOTE: The FDA has not validated any methods that would meet the requirements for any of the above exemptions. If and when the agency does so, it will provide additional guidance as needed for the implementation of such exemptions.

1) Protein blenders, feed manufacturers, and distributors can be exempted from both the cautionary statement and records requirements if, among other things, they:

a) Purchase animal protein products from renderers that certify compliance with a validated manufacturing method to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) (BSE is a TSE), who routinely use a validated test method to detect the presence of the agent that causes TSEs, or who use exclusively a validated method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product; or

b) Comply themselves with these exempting provisions.

2) Protein blenders, feed manufacturers, and distributors can be exempted from the records requirement alone if, among other things, they:

a) Purchase animal protein products that are marked by a permanent method, approved by FDA, indicating the presence of the prohibited materials; or

b) Comply themselves with this marking requirement.

INSPECTIONS FOR COMPLIANCE WITH 21 CFR 589.2000

BEFORE BEGINNING ANY INSPECTION, CHECK WITH YOUR FDA DISTRICT BSE MONITOR TO SEE IF THE FIRM HAS ALREADY BEEN INSPECTED

FEED MANUFACTURERS. PROTEIN BLENDERS. DISTRIBUTORS

I. Does the firm know about the new regulation?

If not, be sure and discuss the requirements of the regulation and leave a copy of the Small Entities Compliance Guide.

II. Does this firm receive and process prohibited material?

In obtaining an answer for this question, one approach is to simply ask, but be sure and include the following questions -

- ★ What kind of protein products do they receive?
- ★ Do they receive products with mammalian protein?
- ★ If yes, what kind of mammalian protein?

A. If the answer to II is NO, they do not receive and process prohibited material, or DO NOT KNOW, do the following -

❶ Do a walk through of the facility, especially looking at the receiving area and the ingredient storage area. Observethe material coming in and any material waiting to be processed. DO YOU SEE ANY PROHIBITED MATERIAL OR ANY INGREDIENT LABELED WITH THE CAUTION STATEMENT REQUIRED BY 589.2000?

❷ Review a representative number [at least ten (IO)] of receiving records and/or invoices for incoming material. DO THESE RECORDS INDICATE RECEIPT OF PROHIBITED MATERIAL? **If the answer here or to #1 is YES, copy the records and document for possible enforcement action.**

❸ Does this firm manufacture feed for ruminant animals? List all of the species for which animal feed is manufactured by this firm.

❹ Determine what procedures or safeguards, if any, the firm has in place to assure they do not receive prohibited material. Describe those safeguards.

B. If the answer to II is YES, they do receive prohibited material, do the following -

❶ Describe the type of prohibited material.

❷ Do a walk through of the facility, especially looking at the receiving and storage area and observe the material coming in and any prohibited material in the ingredient storage area. Is the prohibited material identified?

❸ Does this firm manufacture feed for ruminant animals? List all of the species for which animal feed is manufactured by this firm.

❹ Review a representative number [at least ten (IO)] of records of receipt for incoming prohibited material and for distribution of manufactured feed or feed ingredients containing prohibited material. DO THEY CONTAIN THE REQUIRED INFORMATION? If the answer is NO, copy the records and discuss the requirement with responsible management.

❺ How do they label the feeds or feed ingredients containing prohibited material? Collect a representative copy of the label for each product containing prohibited material. DO THEY BEAR THE REQUIRED CAUTION STATEMENT? **If the answer is NO, document for possible enforcement action.**

❻ Determine what procedures or safeguards, if any, the firm has in place to assure they do not distribute feed containing prohibited material to ruminant feeders. Describe those safeguards.

❼ Make copies or record the information for incoming or outgoing products where the documents suggest possible violations, or otherwise as directed by CVM Assignment Reference #VA 8-BSE. This information may be used to select trace back and trace forward shipments of material for inspection for compliance with 21 CFR 598.2000.

C. Are they or do they plan to process and distribute both feeds or feed ingredients containing prohibited material, and feeds and feed ingredients containing non-prohibited material?

❶ If the answer is **YES,** they will process and distribute both, determine if they are or will be separating the receipt, processing, and storage of the products containing prohibited material from non-prohibited material.

❷ Do a walk through of the incoming material receipt and storage, product processing, and finished product storage, areas. Describe the separation system and procedures to avoid commingling and cross contamination (dust control, separate equipment and/or buildings, other controls on incoming material and finished product identification and storage.)

❸ If they use the same equipment for both products, describe the clean-out procedures.

❹ Does the firm maintain written procedures specifying clean-out and other procedures to separate prohibited material from non-prohibited material from the time of receipt until the time of shipment. If the answer is YES, are they adequate? If the answer is NO **to either question,** discuss this requirement with responsible management.

❺ **If the inspection reveals no controls in place to prevent commingling or cross contamination between product containing prohibited material and product containing non-prohibited material, document for possible enforcement action.**

III. Reporting

1. Complete the checklist "REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR 589.2000."

2. Send 1 copy to each of the following -

a) CVM, Division of Compliance, HFV-235,
7500 Standish Place, Rockville, Maryland 20855
b) BSE Monitor in the FDA District

3. Be sure to report time spent on this inspection under the PAC Code for BSE inspections of feed manufacturers and distributors, or protein blenders (71004G). If the inspection is covering multiple programs, report time spent on this part of the inspection separately.

4. Individual FDA district offices and states may have additional reporting requirements.

IV. What do you do if this firm is not complying with the regulation?

- ★ Issue an FDA 483 or equivalent state document
- ★ Discuss the non-compliance areas with management
- ★ Be sure to leave a copy of the Small Entities Compliance Guide and any other educational materials
- ★ Distribution of product containing prohibited material without the required caution statement should be documented for consideration of a Warning Letter
- ★ Failure to provide measures to prevent commingling and cross contamination of prohibited from non-prohibited material should be documented for consideration of a Warning Letter

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR 589.2000

Firm Name: _____ Date Inspected: _____

Firm Address: _____ Investigator: _____

Firm City/State: _____ District or State Agency: _____

CFN #: _____

❶ Type of firm inspected? (Check all that apply)

Renderer	❑	FDA Licensed Feed Mill	0
Protein Blender	❑	Non-FDA Licensed Commercial Feed Mill	❑
Ruminant Feeder	❑	Ruminant Feeder with On-farm Feed Mill	❑
Hauler/Distributor	❑	Other: _____	

❷ This firm is already aware of 21 CFR 589.2900. YES ❑ NO ❑

Left a copy of the FDA "Guidance for Industry.' YES ❑ NO ❑

❸ Do they receive and manufacture or use products that contain or may contain prohibited material?

YES ❑ NO •I

❹ If the answer to #3 is 'NO,' list the sources of material and describe any safeguards the firm has in place to assure they do not receive prohibited material

_____

_____

_____

_____

For renderers, protein blenders, and feed manufacturers, if the answer to #3 above is 'YES," complete questions #5 through #9 -

❺ Are the products labeled with the caution statement "Do not feed to cattle or other ruminants?"

YES ❑ NO ❑

❻ Does the firm maintain records sufficient to track the materials throughout their receipt, processing, and distribution including -

Date of receipt or purchase, or sale or delivery -	YES ❑ NO ❑
Name and address of the seller -	YES ❑ NO ❑
Name and address of the consignee -	YES ❑ NO ❑
Identification of the product -	YES ❑ NO ❑
Quantity -	YES ❑ NO ❑
Copies are available for inspection and copying -	YES ❑ NO ❑

❼ Is this firm processing or manufacturing and distributing both product containing prohibited material and product containing non-prohibited material? YES o NO ❑

8 If the answer to #7 is "YES," does the firm have a system in place to avoid commingling and dross contamination?

YES ☐ NO •I

Describe the separation system or clean-out process and any procedures to avoid commingling and dross contamination.

_____

_____

_____

9 Does the firm have any safeguards in place to assure that outgoing product containing prohibited material is not shipped to ruminant feeders? YES ☐ NO ☐

Describe those safeguards?

_____

_____

_____

10 Are ruminant feeders doing the following -

Observing the caution statement on feeds containing prohibited material	YES ❑	☐
Maintaining copies of labeling for feeds containing animal protein	YES •I	❑
Maintaining copies of purchase invoices for feeds containing animal protein	YES ❑	☐

If you found any areas or items of non-compliance with 21CFR 589.2000, please list below -

_____

_____

Name and title of person interviewed: _____

Did the firm or individual make any commitments to correct their non-compliance? YES •I NO ☐

List those commitments - _____

_____

Are you attaching any further descriptions or any exhibits or records and/or labeling? YES ❑ NO ☐

Follow-up:
- Needs additional educational material 0
- Reinspect to confirm corrections 0 — Target date for reinspection: _____
- Recommend Warning Letter 0
- Other: _____